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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,296	02/06/2006	Narayanan Badri Viswanathan	RLL-310US	8748

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Ranbaxy Inc.
Intellectual Property Department
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EXAMINER
WESTERBERG, NISSA M

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
01/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

general.ip.mailbox@ranbaxy.com

Office Action Summary	Application No.	Applicant(s)	
	10/532,296	VISWANATHAN ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 5 - 10, 18, 29, 35, 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5 - 10, 18, 29, 35, 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed November 9, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 - 2nd Paragraph

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "the single functional layer" in line 2. There is insufficient antecedent basis for this limitation in the claim.

3. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because it is unclear what is meant by the term “one or more non-functional layers surrounding the tablet”. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 7, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that the term "one or more non-functional layers surrounding the tablet" has been described as cosmetic coating and therefore is solely for cosmetic purposes and does not affect the release of alfuzosin, which is the function of the dosage form.

These arguments are unpersuasive. As previously described, one example of such a layer was provided in the specification and because the specification indicated that the one or more non-functional layers may include a cosmetic coating. This is not a limiting definition. Also, the definition given by Applicant does not make sense. Even a layer added with the purpose of changing only the cosmetic appearance of the tablet will affect the release of the alfuzosin as the nonfunctional layer must dissolve or the solvent permeate through the cosmetic layer to reach the functional layer. That time lapse will affect alfuzosin release from the dosage form.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 5 - 10 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Maggi et al. (US 6,149,940). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 7, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that the invention described by Maggi is characterized that by rapid and considering swelling of the layers upon contact with gastric juices to increase the volume of the pharmaceutical preparation so the

preparation remains in the stomach for longer. Maggi teaches away from the use of “preparations such as hydrophilic matrices, which break down or swell" (col 1, ln 42 - 44) and have major drawbacks. The present invention comprises a single functional layer comprising alfuzosin, and a releasing retarding agent that is composed of both HPMC (hydroxypropylmethyl cellulose) and HPC (hydroxypropyl cellulose). The HPMC and HPC may generally be deemed a hydrophilic matrix preparation, and thus one skilled in the art would not be motivated to modify the disclosure of Maggi as such a modification would be contrary to the overall purpose of the invention. There is also no motivation to reduce the number of functional layers down to a single functional layer in order to simplify the manufacturing process.

These arguments are unpersuasive. The quote reproduced above by Applicant (col 1, ln 42 – 44) was referring to other compositions of the prior art and not the inventive compositions of Maggi. Layer 2 is the layer of the inventive composition which contains the alfuzosin and is formulated with hydrophilic polymers (col 2, ln 12 – 15). To further expand and emphasis this point, Maggi also states “the polymeric substances which are used in the layers **1** and **3**, and which may also be used in layer **2** are biocompatible and have hydrophilic properties” and then a Markush group of such polymers is given, a list which specifically includes HPMC and HPC (col 2, ln 6 0 – col 3, ln 1). Therefore, Maggi does NOT teach away from the inclusion of hydrophilic polymers such as HPMC or HPC as in describing the inventive compositions, the inclusion of such hydrophilic polymers is positively recited.

The instant claims use the open language of "comprising". Claim 1 therefore requires 1 layer with the recited ingredients, and other functional or non-functional layers are not excluded, such as is recited in dependent claim 18. Therefore, no motivation need be present to remove these layers as such a modification is not required by the instant claims. The layers without drug read on a nonfunctional layer in that these layers do not contain the pharmaceutically active ingredient, and therefore are nonfunctional in that those layers do not provide the therapeutic function provided by alfuzosin to the subject who took the alfuzosin tablet.

8. Claims 1, 5 – 10 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Maggi et al. (US 6,149,940) further in view of Remington The Science and Practice of Pharmacy p 894 (2000). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 7, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Remington does not disclose the advantages of using a hydrophilic matrix formulation composed of a single functional layer and would not motivate one to formulate an alfuzosin dosage form.

This argument is unpersuasive. As discussed in greater detail above, Maggi et al. does positively recite the inclusion of the hydrophilic polymer HPMC and HPC in a layer with the alfuzosin active ingredient to prepare a single functional layer. Therefore, Remington does not need to remedy that deficiency. The inclusion of a cosmetic layer is

taught by Remington to improve the appearance of the formulation and providing identity information.

9. Claims 1 and 5 – 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bordes et al. (FR 2820319; all citations from US 2004/0115259). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 7, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Bordes discloses a formulation that is a floating tablet. Border highlights the proportion of excipient relative to that of the active principle as not being obvious that such a ratio could lead to flotation and control of the release profile as indicated. In light of this, substitution or alteration of the excipients used in the formulation is not obvious and any alteration may affect the precise ratio of excipient to active ingredient, a critical feature of the formulation. There is no teaching that both HPMC and HPC may be used in combination in a single function layer. Any modification may affect the underlying goal of the invention - a product that floats in the stomach. The person skilled in the art would heed the warning and would not be motivated to substitute and/or add HPC to the functional layer as such a combination may effect the compression necessary to enable the dosage form to float.

These arguments are unpersuasive. Border highlights the ratio of excipient to active substance, not the identity of those excipients in the formulation, as determining the flotation characteristics of the formulation. In light of the teaching elsewhere in the

specification that the HPMC and/or derivatives of povidone and of polyvinyl acetate can be present in amounts ranging from 50.00 to 99.00% of the mass of the tablet, a disintegrating agent in amounts ranging from 1 to 50% by weight and other excipients such as small proportions of HPC to modify the kinetics of release (¶¶ [0072] - [0074]), Bordes et al. indicates that the ratio that enables flotation is not a narrow window as anywhere between half and 99.00% of the tablet remains within the scope of the formulations contemplated. HPC is explicitly mentioned as an excipient, which can be added in small proportion to modify the release kinetics of the alfuzosin from the HPMC and alfuzosin layer. Based on the teachings of the actual amounts of various ingredients present in the specification, a variety of excipients in a relatively wide range of amounts and therefore ratios to the active principle will result in a dosage form that floats.

10. Claims 1 and 5 – 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bordes et al. as applied to claims 1 and 5 – 10 above, and further in view of Lowey (US 4,259,314). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 7, 2009 and those set forth below.

Applicant traverses this rejection in addition to the grounds discussed above in regards to Bordes on the grounds that Lowey does not disclose alfuzosin, the ratio of excipient to active ingredient deemed critical by Border would not be addressed and a person skilled in the art would not know how to modify Bordes in light of Lowey to reach the present invention.

These arguments are unpersuasive. As discussed in greater detail above, Bordes et al. indicates that wide ranging amounts of the HPMC are within the scope of formulations that float, and the small amounts HPC can be included to modify the release kinetics. Lowey explicitly teaches a combination of HPMC and HPC as useful to control the release of a wide variety of drugs, a combination which is implied but not explicitly taught by Bordes et al. As Bordes et al. discloses HPMC as a controlled release material, possibly in conjunction with HPC, as a sustained release matrix for alfuzosin, Lowey does not need to disclose that specific drug.

11. Claims 1, 5 – 10 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bordes et al. as applied to claims 1 and 5 – 10 above, and further in view of Remington the Science and Practice of Pharmacy (2000). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 7, 2009 and those set forth herein.

Applicant traverses this rejection on the grounds discussed above in regards to Bordes et al. and those deficiencies are not cured by Remington. Remington provides no motivation except to add an additional coating to the single functional layer and so does not motivate one skilled in the art to alter the excipient ratio through the inclusion of both HPMC and HPC in the functional layer.

These arguments are unpersuasive. The lack of deficiencies in Bordes et al. was discussed in greater detail above so Remington does not need to motivate the inclusion of HPC in the layer with alfuzosin and HPMC. Therefore this rejection is maintained.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW